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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,906	02/14/2007	Angeline Ingrid Bartholomeusz	19781	7415

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,906	BARTHOLOMEUSZ ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,37 and 39-53* is/are pending in the application.

4a) Of the above claim(s) *1-34, 39-49 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37,50,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed January 7, 2010 in response to the Office Action of October 8, 2009 is acknowledged and has been entered. Claims 35 and 37 have been amended. Claims 36 and 38 have been canceled. Rejection of canceled claims is moot. New claims 53 and 54 have been added. Claims 1-34, 39-49 and 52 are withdrawn. Claims 35, 37, 50 and 53-54 are under examination in this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the UnitedStates.

Rejection of Claims 35, 37, 50 and 51 under 35 U.S.C. 102(b) as being anticipated by Bartholomeusz (WO 2003/066841 A1 August 14, 2003) **is maintained. New Claims 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartholomeusz (WO 2003/066841 A1 August 14, 2003).**

Applicant amended the claims to delete nucleoside analog LMV and the mutation rtM204V and to add "exhibit resistance", "decreased sensitivity" and "or reduced sensitivity". New claim 53 further defines that the mutation is indicative of resistance to ADV or TFV and that the variant exhibits the decreased sensitivity to ADV or TFV. The rejection is maintained and the new claims are rejected because Bartholomeusz discloses a method for determining the potential for an HBV to exhibit reduced sensitivity to a nucleoside or nucleotide analog ADV and TFV, comprising isolating DNA from HBV and screening for a mutation in the nucleotide

sequence encoding HBV DNA polymerase resulting in an amino acid substitution in domains F and A through E, F and G and A through E and associated with resistance to LMV, wherein the mutation is the DNA polymerase is rtL180M and wherein the mutation in the surface protein is sI195M (see claims 1-24, Table 1, page 6, lines 20-25, page 7, page 18, page 27, 28, page 30, lines 1-6, page 33, lines 4-19, Example 5, Example 16 and Figure 11).

Thus by this disclosure Bartholomeusz anticipates the present claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35, 37, 50, 51, 53 and 54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-18 of U.S. Patent No.6, 555,311. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a method for determining the potential

for an HBV to exhibit resistance or reduced sensitivity to a nucleoside or nucleotide analog selected from ADV, TFV and/or FTC or optionally other nucleoside or nucleotide analogs, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in the nucleotide sequence encoding HBV DNA polymerase resulting in at least one amino acid substitution, deletion and/or addition in any one or more of domains F and A through E or a region proximal thereto of said DNA polymerase and associated with resistance or decreased sensitivity to one or more of ADV, TFV and/or FTC wherein the presence of such a mutation is an indication of the likelihood of resistance or reduced sensitivity to said one or more of ADV, TFV or FTC wherein the mutation screened for in the DNA polymerase and the claims of the U.S. Patent No.6, 555,311 are drawn to a method for determining the potential for an HBV to exhibit, relative to an isolated wild-type HBV, reduced sensitivity to at least one of lamivudine, penciclovir and famciclovir, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in a nucleotide sequence encoding the B domain of HBV polymerase corresponding to amino acid residues 495-535 of a wild-type HBV polymerase, with said mutation resulting in at least one amino acid substitution, deletion and/or addition in said B domain, wherein the presence of such a mutation is an indication of the potential of reduced sensitivity of said HBV to at least one of lamivudine, penciclovir and famciclovir.

Claim 35, 37, 50, 51, 53 and 54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-18 and 26-58 of copending Application No. 11,932,410. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of the present and the copending application are drawn to a method for determining the potential for an HBV to exhibit resistance or reduced sensitivity to a nucleoside or nucleotide analog selected from ADV, TFV and/or FTC or optionally other nucleoside or nucleotide analogs, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in the nucleotide sequence encoding HBV DNA polymerase resulting in at least one amino acid substitution, deletion and/or addition in any one or more of domains F and A through E or a region proximal thereto of said DNA polymerase and associated with resistance or decreased sensitivity to one or more of ADV, TFV and/or FTC wherein the presence of such a mutation is an indication of the likelihood of resistance or reduced sensitivity to said one or more of ADV, TFV or FTC wherein the mutation screened for in the DNA polymerase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 35, 37, 50, 51, 53 and 54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-60 of copending Application No. 11,913,106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present and the copending application are drawn to a method for determining the potential for an HBV to exhibit resistance or reduced sensitivity to a nucleoside or nucleotide analog selected from ADV, TFV and/or FTC or optionally other nucleoside or nucleotide analogs, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in the nucleotide sequence encoding HBV DNA polymerase resulting in at least one amino acid substitution, deletion and/or

addition in any one or more of domains F and A through E or a region proximal thereto of said DNA polymerase and associated with resistance or decreased sensitivity to one or more of ADV, TFV and/or FTC wherein the presence of such a mutation is an indication of the likelihood of resistance or reduced sensitivity to said one or more of ADV, TFV or FTC wherein the mutation screened for in the DNA polymerase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 35, 37, 50, 51, 53 and 54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 79-80, 87-88 and 90 of copending Application No. 11,932,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present and the copending application are drawn to a method for determining the potential for an HBV to exhibit resistance or reduced sensitivity to a nucleoside or nucleotide analog selected from ADV, TFV and/or FTC or optionally other nucleoside or nucleotide analogs, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in the nucleotide sequence encoding HBV DNA polymerase resulting in at least one amino acid substitution, deletion and/or addition in any one or more of domains F and A through E or a region proximal thereto of said DNA polymerase and associated with resistance or decreased sensitivity to one or more of ADV, TFV and/or FTC wherein the presence of such a mutation is an indication of the likelihood of resistance or reduced sensitivity to said one or more of ADV, TFV or FTC wherein the mutation screened for in the DNA polymerase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 35, 37, 50, 51, 53 and 54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-70 of copending Application No. 12,346,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present and the copending application are drawn to a method for determining the potential for an HBV to exhibit resistance or reduced sensitivity to a nucleoside or nucleotide analog selected from ADV, TFV and/or FTC or optionally other nucleoside or nucleotide analogs, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in the nucleotide sequence encoding HBV DNA polymerase resulting in at least one amino acid substitution, deletion and/or addition in any one or more of domains F and A through E or a region proximal thereto of said DNA polymerase and associated with resistance or decreased sensitivity to one or more of ADV, TFV and/or FTC wherein the presence of such a mutation is an indication of the likelihood of resistance or reduced sensitivity to said one or more of ADV, TFV or FTC wherein the mutation screened for in the DNA polymerase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 35, 37, 50, 51, 53 and 54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 12,384,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present and the copending

application are drawn to a method for determining the potential for an HBV to exhibit resistance or reduced sensitivity to a nucleoside or nucleotide analog selected from ADV, TFV and/or FTC or optionally other nucleoside or nucleotide analogs, said method comprising isolating DNA or corresponding mRNA from said HBV and screening for a mutation in the nucleotide sequence encoding HBV DNA polymerase resulting in at least one amino acid substitution, deletion and/or addition in any one or more of domains F and A through E or a region proximal thereto of said DNA polymerase and associated with resistance or decreased sensitivity to one or more of ADV, TFV and/or FTC wherein the presence of such a mutation is an indication of the likelihood of resistance or reduced sensitivity to said one or more of ADV, TFV or FTC wherein the mutation screened for in the DNA polymerase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/
Examiner, Art Unit 1648